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## **DEPARTMENT OF THE TREASURY**

### **Alcohol and Tobacco Tax and Trade Bureau**

#### **27 CFR Parts 4, 5, and 7**

**[Docket No. TTB-2010-0008; T.D. TTB-103; Ref: Notice No. 111]**

**RIN 1513-AB79**

### **Disclosure of Cochineal Extract and Carmine in the Labeling of Wines, Distilled Spirits, and Malt Beverages**

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau is revising its regulations to require the disclosure of the presence of cochineal extract and carmine on the labels of any alcohol beverage product containing one or both of these color additives. This rule responds to a final rule issued by the Food and Drug Administration. Consumers who are allergic to cochineal extract or carmine will now be able to identify and thus avoid alcohol beverage products that contain these color additives.

**DATES:** Effective Date: [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Transitional rules are provided which will require compliance by April 16, 2013. Voluntary compliance with this final rule, including making any required labeling changes, may begin immediately.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Gesser, telephone 202–453–1039, ext. 292 or Joanne C. Brady, telephone 202–453–1039, ext. 291; Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Box 12, Washington, DC 20005.

**SUPPLEMENTARY INFORMATION:**

**I. TTB’s Authority to Prescribe Alcohol Beverage Labeling Regulations**

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), codified at 27 U.S.C. 205(e), sets forth standards for regulation of the labeling of wine (containing at least 7 percent alcohol by volume), distilled spirits, and malt beverages, generally referred to as “alcohol beverage products” throughout this final rule. This section gives the Secretary of the Treasury the authority to issue regulations to prevent deception of the consumer, to provide the consumer with “adequate information” as to the identity and quality of the product, to prohibit false or misleading statements, and to provide information as to the alcohol content of the product.

Section 105(e) of the FAA Act also requires that a person obtain a certificate of label approval (COLA) for all wines, distilled spirits, or malt beverages introduced into interstate or foreign commerce before bottling the product or removing the product from customs custody, in accordance with regulations prescribed by the Secretary. The labeling provisions of the FAA Act also give the Secretary the authority to prohibit, irrespective of falsity, statements relating to age, manufacturing processes, analyses, guarantees, and scientific or irrelevant matters that are likely to mislead the consumer. In the case of malt

beverages, the labeling provisions of the FAA Act apply only if the laws of the State into which the malt beverages are to be shipped impose similar requirements.

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01 (Revised), dated January 21, 2003, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

## **II. Background**

In 1987, the Food and Drug Administration (FDA) and the Bureau of Alcohol, Tobacco and Firearms (ATF), TTB's predecessor agency, entered into a memorandum of understanding (published in the **Federal Register** at 52 FR 45502, November 30, 1987), to clarify the enforcement responsibilities of each agency with respect to alcohol beverages. ATF agreed that "when FDA has determined that the presence of an ingredient in food products, including alcoholic beverages, poses a recognized public health problem, and that the ingredient or substance must be identified on a food product label, ATF would initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages consistent with ATF's health policy with respect to alcoholic beverages." TTB operates under the same memorandum of understanding with FDA.

Cochineal extract and carmine are color additives that are permitted for use in foods, including alcohol beverage products, in the United States. The FDA has listed these color additives, and the conditions for their safe use in foods, in § 73.100 of the FDA regulations (21 CFR 73.100). On January 5, 2009, FDA published a final rule in the **Federal Register** (74 FR 207) requiring cochineal extract and carmine to be declared by name on the labels of all food and cosmetic products containing one or both of these color additives. FDA explained that this requirement was adopted in response to reports of severe allergic reactions, including anaphylaxis, to foods containing these color additives. The FDA final rule does not require food or cosmetics labels to disclose that these color additives are derived from insects.

Accordingly, on November 3, 2010, TTB published in the **Federal Register** a Notice of Proposed Rulemaking, Notice No. 111, (75 FR 67669) which proposed to require cochineal extract and carmine to be listed on the labels of any alcohol beverage product containing one or both of these color additives. Specifically, TTB proposed amending §§ 4.32, 5.32, and 7.22 of Title 27 Code of Federal Regulations to require that all alcohol beverage products containing cochineal extract or carmine list the additive(s) prominently and conspicuously on the brand label or on a back label using its respective common or usual name “cochineal extract” or “carmine.” Beginning on the implementation date, an alcohol beverage product containing cochineal extract or carmine would have to bear the mandatory statement on its label at the time of its removal from bond or from customs custody. TTB sought comments on the proposal as

outlined in Notice No. 111. TTB specifically sought comments from affected industry members as to whether an implementation date beginning 90 days from the date of the final rule would provide a sufficient amount of time to incorporate these changes. Commenters had until January 3, 2011, to respond to the proposed rule.

During the comment period, TTB received a request from the Distilled Spirits Council of the United States, Inc. (DISCUS), a national trade association that represents producers and marketers of distilled spirits and importers of wines sold in the United States, to extend the comment period for 60 days to allow more time to collect and review data from domestic and foreign companies regarding the issues raised in the proposed rule.

In response to this request, on December 29, 2010, TTB published in the **Federal Register** Notice No. 114 (75 FR 81949) which extended the comment period for Notice No. 111 an additional 60 days. Accordingly, the comment period for the proposal outlined in Notice No. 111 closed on March 4, 2011.

### **III. Discussion of Comments and Agency Responses**

TTB received a total of six responses to TTB Notice No. 111, in addition to the request to extend the comment period discussed above. The commenters include three individuals, two trade associations (DISCUS and the International Association of Color Manufacturers (IACM)), and one alcohol beverage importer. Two of the individual commenters commented in support of TTB's proposal to require the disclosure of these color additives, which they characterize as known allergens, on alcohol beverage labels. Furthermore, none of the other

commenters opposed TTB's proposal to require the disclosure of cochineal extract or carmine on alcohol beverage labels.

With regard to the number of products that would be affected by the proposed rule, the comments did not provide specific numbers. However, DISCUS stated that it believed that "several" alcohol beverage products would be affected, and the IACM stated that "few alcohol beverage products" contained cochineal extract. Based on the comments, TTB has no reason to believe that a substantial number of industry members would be affected by the proposed rule. Nonetheless, several commenters suggested modifications to the proposed rule. The following is a summary of those comments and TTB's responses.

#### Comments Concerning Disclosure of the Origin of the Color Additives

One individual commenter supported the requirement to list cochineal extract and carmine on alcohol beverage labels, but suggested that the TTB rule should go further and require statements on labels that disclose that the additives are animal products derived from an insect. The commenter stated that while industry groups may not want to list the source of the dye for fear that consumers would find the thought of insect derivatives unappealing, vegetarians or people of certain faiths may be interested in this information so they can avoid consuming products that conflict with their beliefs.

IACM stated that it did not oppose the disclosure of cochineal extract and carmine on alcohol beverage labels. However, IACM opposed any requirement to disclose that the additives are derived from insects. IACM noted that FDA (in its proposed rule published in the **Federal Register** at 71 FR 4839 on

January 30, 2006) specifically stated it saw no need to require the declaration of insect origin for cochineal extract and carmine, as information on the origin of the additives was readily available to those who wanted it.

TTB Response

As previously noted, the FDA final rule does not require that food or cosmetics labels disclose that these color additives are derived from insects. In the preamble to its final rule, which was published in the **Federal Register** on January 5, 2009 (74 FR 207), FDA explained that it did not agree with the commenters who suggested that declaring these color additives by name would provide insufficient information to consumers who choose to avoid products containing these additives. Similarly, TTB does not believe that the source of the color additives needs to be listed on the alcohol beverage label in order for consumers to have adequate information about the product. The purpose of the rule is to allow persons with sensitivities to cochineal extract or carmine the opportunity to avoid ingestion of or contact with these additives. Providing the common name of the color additives on the label will provide sufficient information to all consumers, including those with sensitivities to the additives as well as those who for other reasons wish to avoid these additives. Accordingly, TTB is not adopting this requested change in the final rule.

### Comments Concerning the Implementation Period

In their respective comments, the two trade associations and the alcohol beverage importer suggested that TTB extend the proposed 90-day implementation period in order to lessen the burden on affected industry members. IACM commented that while it does not anticipate that the proposed rule would have a substantial economic impact on color additive manufacturers, TTB should consider extending the implementation date from 90 days to 180 days after the date the final rule is published in order to reduce the burden on small companies that are already facing limited financial resources due to the sluggish economy.

DISCUS stated in its comment that the proposed 90-day implementation period would not provide sufficient time to comply with the proposed labeling requirement. DISCUS suggested that TTB adopt a phased-in approach similar to the one which implemented the sulfite labeling disclosure. For that rule, TTB's predecessor agency, ATF, provided a one year transition period to fully implement the new requirement.

The alcohol beverage importer stated in his comment that he currently imports a product that contains cochineal extract, and that he currently uses a TTB-approved label for this product that states that the product contains artificial color. He stated that although he does not oppose TTB's proposal, he is concerned about the implementation date, as he has a large supply of labels for this product. The commenter requested that the proposed labeling requirements be implemented no less than one year after the date the final rule is published, to



allow more time to use up the labels. Alternatively, he requests that TTB grant him permission to use up the rest of his previously approved labels, as he believes the "artificial color" statement on the label will prevent consumers from being misled.

#### TTB Response

After careful consideration of the comments concerning the implementation period, TTB agrees that a longer transition period is appropriate. A longer implementation period will allow more time for bottlers and importers to exhaust their label stocks before the new requirements become effective. Accordingly, the requirement to disclose the presence of cochineal extract and carmine by name on the labels of any alcohol beverage product containing one or both of these color additives will become mandatory for products that are removed on or after one year from the publication of this final rule in the **Federal Register**. TTB believes this longer implementation period will provide sufficient time for industry members to comply with the new labeling requirement, and is the most appropriate alternative to address the concerns expressed by commenters regarding the implementation date.

Bottlers and importers may begin voluntarily complying with the requirements immediately upon publication of this final rule.

#### Comments Concerning COLA Requirements for New Label Disclosure

In its comment, DISCUS also requested that TTB consider permitting industry members with existing approved COLAs covering affected products to revise the labels solely to include the mandatory declaration without applying for

and receiving new label approvals. DISCUS also suggested that TTB allow the addition of a separate strip or neck label that shows the mandatory declaration, instead of having to apply for and receive a new label approval.

#### TTB Response

TTB agrees with the suggestion by DISCUS that if a label is merely being changed to include the new label disclosure, without altering existing information on the label, an application for a new COLA would be unnecessary. Accordingly, by publication of this document in the **Federal Register**, TTB is adopting the policy that labels covered by existing approved COLAs which are revised solely to include the mandatory cochineal or carmine declaration are considered approved by TTB and do not require further approval. Bottlers and importers also do not require a new COLA to add a new neck or strip label solely to comply with the mandatory cochineal or carmine declaration. Any other changes to the label, other than those permitted in accordance with the instructions listed on the COLA application (TTB F 5100.31 or the electronic COLA submission through COLAS Online) will require the submission of a new COLA for approval.

#### **IV. Changes to TTB Regulations**

As proposed in TTB Notice No. 111, this final rule amends §§ 4.32, 5.32(b), and 7.22(b) of the TTB regulations to require the disclosure of the presence of cochineal extract and carmine on the labels of any alcohol beverage product containing one or both of these color additives. With regard to § 7.22(b), TTB is incorporating the amendment in paragraph (b)(5) instead of (b)(8) as originally proposed, and, for clarity, TTB has made some changes from the

language originally proposed in the amendments to §§ 4.32, 5.32(b)(6), and 7.22(b). The regulations permit the disclosure to appear on the front, back, neck, or strip label and require that the disclosure be displayed prominently and conspicuously.

## **V. Regulatory Analysis and Notices**

### **A. Regulatory Flexibility Act**

TTB certifies under the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) that the final rule will not have a significant economic impact on a substantial number of small entities. The final rule will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities, because relatively few alcohol beverages are made using cochineal extract or carmine as color additives. Furthermore, in response to comments about allowing sufficient time to use up existing inventories of labels, the final rule provides for a one-year implementation period. Accordingly, a regulatory flexibility analysis is not required.

### **B. Executive Order 12866**

This rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, a regulatory assessment is not required.

### C. Paperwork Reduction Act

The collection of information contained in this final regulation has been reviewed and approved by the Office of Management and Budget (OMB) in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1513–0087.

The collection of information in this regulation is in 27 CFR §§ 4.32, 5.32, and 7.22, and involves mandatory disclosures of information on labels. This information is required to prevent deception of the consumer and to provide the consumer with adequate information as to the identity and quality of the alcohol beverage product. The likely respondents are businesses or other for-profit entities, including partnerships, associations, and corporations.

This information constitutes only a portion of the labeling information on alcohol beverages required under authority of the FAA Act and approved under control number 1513–0087.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

### **VI. Drafting Information**

The principal authors of this document are Lisa M. Gesser and Joanne C. Brady, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau.

## **List of Subjects**

### **27 CFR Part 4**

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

### **27 CFR Part 5**

Administrative practice and procedure, Advertising, Customs duties and inspection, Distilled spirits, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices.

### **27 CFR Part 7**

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Malt Beverages, Reporting and recordkeeping requirements, Trade practices.

## **Amendments to the Regulations**

For the reasons discussed in the preamble, TTB amends 27 CFR, chapter I, parts 4, 5, and 7, as set forth below:

### **PART 4—LABELING AND ADVERTISING OF WINE**

1. The authority citation for 27 CFR part 4 continues to read as follows:

**Authority:** 27 U.S.C. 205, unless otherwise noted.

2. In § 4.32, add a new paragraph (d) to read as follows:

**§ 4.32 Mandatory label information.**

\* \* \* \* \*

(d) Declaration of cochineal extract or carmine. There shall be stated on a front label, back label, strip label, or neck label a statement that the product contains the color additive cochineal extract or the color additive carmine, prominently and conspicuously, using the respective common or usual name (“cochineal extract” or “carmine”), where either of the coloring materials is used in a product that is removed on or after April 16, 2013. (For example: “Contains Cochineal Extract” or “Contains Carmine” or, if applicable, “Contains Cochineal Extract and Carmine”).

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**PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS**

3. The authority citation for 27 CFR part 5 continues to read as follows:

**Authority:** 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

4. In § 5.32, add a new paragraph (b)(6) to read as follows:

**§ 5.32 Mandatory label information.**

\* \* \* \* \*

(b) \* \* \*

(6) A statement that the product contains the color additive cochineal extract or the color additive carmine, prominently and conspicuously, using the respective common or usual name (“cochineal extract” or “carmine”), where either of the coloring materials is used in a product that is removed on or after April 16, 2013. (For example: “Contains Cochineal Extract” or “Contains

Carmine” or, if applicable, “Contains Cochineal Extract and Carmine”). The statement that the product contains the color additive cochineal extract or the color additive carmine may appear on a strip label or a neck label in lieu of appearing on the brand label or back label.

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## **PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES**

5. The authority citation for 27 CFR part 7 continues to read as follows:

**Authority:** 27 U.S.C. 205.

6. In § 7.22, a new paragraph (b)(5) is added to read as follows:

### **§ 7.22 Mandatory label information.**

\* \* \* \* \*

(b) \* \* \*

(5) A statement that the product contains the color additive cochineal extract or the color additive carmine, prominently and conspicuously, using the respective common or usual name (“cochineal extract” or “carmine”), where either of the coloring materials is used in a product that is removed on or after April 16, 2013. (For example: “Contains Cochineal Extract” or “Contains Carmine” or, if applicable, “Contains Cochineal Extract and Carmine”). The statement that the product contains the color additive cochineal extract or the color additive carmine may appear on a strip label or a neck label in lieu of appearing on the brand label or back label.

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Signed: March 12, 2012.

**John J. Manfreda,**

Administrator.

Approved: March 12, 2012.

**Timothy E. Skud,**

Deputy Assistant Secretary  
(Tax, Trade, and Tariff Policy).

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